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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/849,905 | 05/04/2001 | David Alan Witt | 13946(END-696) | 9106 |
| 7590 | 01/28/2004 | | EXAMINER | |
| Leopold Presser, Esq. Scully, Scott, Murphy & Presser 400 Garden City Plaza Garden City, NY 11530 | | | ODLAND, KATHRYN P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3743 | |
| DATE MAILED: 01/28/2004 S | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|----------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/849,905 | WITT ET AL. |
| | Examiner Kathryn Odland | Art Unit 3743 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 December 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated December 1, 2003. Claims 1-17 are pending.

1. The amendment filed December 1, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: an elongated tubular member that transmits ultrasonic energy to the end effector.

Applicant is required to cancel the new matter in the reply to this Office Action. This limitation appears to contradict the specification, which states on page 11, "As shown in Fig. 3, rings 38 are formed from a silastic material and spaced along the length of the blade extender 21 at the nodes thereof so as to prevent the dispersion of ultrasonic waves to the tube 22.

Response to Arguments

2. Applicant's arguments filed December 1, 2003 have been fully considered but they are not persuasive. Applicant argues that neither Mastri nor Miyawaki disclose:

"...an end effector including a blade and clamp means for the engagement of tissues located therebetween; an elongated shaft element having said end effector **arranged** at a first end thereof."

Clearly both Mastri as well as Miyawaki disclose this limitation. Regarding Mastri's disclosure of an end effector including a blade and clamp means for the engagement of tissues located therebetween; an elongated shaft element having said end effector **arranged** at a first end thereof, Mastri clearly discloses an end effector including a blade (58, 59) and clamp means (60) for the engagement of tissues located therebetween, where discussion of tissue contact is discussed in column 4, for example. Further, Mastri discloses an elongated shaft element (50) having said end effector **arranged** at a first end thereof. The term "arrange" is defined as to put into a specific order or relation according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. There is not requirement that the elongated shaft element directly unite. Regarding Miyawaki's disclosure of end effector including a blade and clamp means for the engagement of tissues located therebetween; an elongated shaft element having said end effector **arranged** at a first end thereof, Miyawaki clearly discloses end effector including a blade (251a) and clamp means (282) for the engagement of tissues located therebetween. Further, Miyawaki clearly discloses an elongated shaft element (252) having said end effector **arranged** at a first end thereof. Again, the term "arrange" is defined as to put into a specific order or relation according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. There is not requirement that the elongated shaft element directly unite.

Further, applicant argues that Miyawaki does not disclose, "said tubular member biasing said clamp so as to cause said blade and clamp means to selectively open and

close relative to each other." However element (231) limits the range of motion to the shaft (252). Thus, the motion is directed in the axial direction, thus, biasing to enable the blade and clamp assembly to selectively open and close.

Claim Rejections - 35 USC § 112

The 35 U.S.C. 112 rejections presented in the office action dated June 26, 2003 have been withdrawn. However, the following apply.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended claim 2 and added claim 16 to include the limitation where the elongated tubular member transmits ultrasonic energy to the end effector. This limitation appears to contradict the specification, which states on page 11, "As shown in Fig. 3, rings 38 are formed from a silastic material and spaced along the length of the blade extender 21 at the nodes thereof so as to prevent the dispersion of ultrasonic waves to the tube 22. It appears that it was intended to state that the elongated shaft element transmits ultrasonic energy. Thus, an art rejection has not been applied. **Nonetheless, the prior rejection of Paper No. 5 still applies for the claims as previously presented.**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 2 and 16 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 2 and 16 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Paper No. 8 filed December 1, 2003. In that paper, applicant has stated that the elongated tubular member transmits ultrasonic energy to the end effector and this statement indicates that the invention is different from what is defined in the claim(s) because it does not appear that the elongated tubular member transmits ultrasonic energy.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Olympus

Optical in JP 8275952.

Regarding claim 17, Olympus Optical disclose an end effector including blade (11) and clamp means (12) for the engagement of tissues located therebetween, as recited throughout the specification, in the abstract and seen in figures 1-10; an elongated shaft element (such as 4 and associated components) having the end effector arranged at a first end thereof, the clamp means (12) being pivotally attached to the first end of the elongated shaft element, as seen in figures 1-10; an elongated tubular member (such as 20) extending about the elongated shaft element (4 and associated components) in coaxial relationship, the clamp means (12) being pivotable relative to the blade and tubular member, the elongated tubular member (such as 20) having a first end in operative engagement with the end effector, as recited throughout the specification, abstract and seen in figures 1-10; and a handle portion in operatively connected to one or more of the elongated shaft element and elongated tubular member for actuating the blade and clamp means between open and close positions, as recited throughout the specification, abstract and seen in figure 1, for example.

9. Claims 1, 5, 7-12, and 14 rejected under 35 U.S.C. 102(b) as being anticipated by Mastri et al. in US Patent No. 6,024,750.

Mastri et al. discloses an ultrasonic surgical instrument having an end effector including blade (58, 59) and clamp means (60) for the engagement of tissues located therebetween, as recited in column 3, lines 35-67 and seen in figures 3 and 4; an elongated shaft element (such as 50) having the end effector arranged at a first end thereof; an elongated tubular member (such as 46)

extending about the elongated shaft element in coaxial relationship, the clamp means (60) being movable relative to the blade (58,59) and the tubular member (46), the elongated tubular member (46) having a first end in operative engagement with the end effector, as recited in column 3, lines 35-67, column 4 and seen in figure 4; a handle portion (generally at 22b, 22a, and 36) for receiving second opposite ends of respectively the elongated shaft element (50) and the elongated tubular member (46), the handle portion including finger-actuatable scissors-like thumb and finger ring structure for imparting axial displacement between the elongated shaft element and the elongated tubular member, the tubular member biasing the clamp means so as to cause the blade and clamp means to selectively open and close relative to each other; as recited in column 4, lines 45-67, column 5, lines 1-34 and seen in figures 5-7; an elongated tubular member (46) that has the second end thereof slidably journaled in the handle portion (generally at 22b, 22a, and 36), the elongated shaft element (50) being fixedly attached to the handle portion, the thumb and finger ring assembly having a pivotable portion operatively connected with the second end of the elongated tubular member, whereby actuation of the pivotable portion imparts the axial displacement to the elongated tubular member (46) relative to the elongated shaft element (50), as recited in column 4, lines 45-67, column 5, lines 1-34 and seen in figures 5-7; a first end of the elongated shaft element (50) and of the elongated tubular member (46) that have a cooperative camming structure for selectively opening and closing the blade and clamp

means responsive to relative axial movement between the shaft element (50) and tubular member (46), as recited in column 3, lines 34-67, column 4, column 5, lines 1-34 and seen in figures 3-7; a blade (58, 59) of the end effector that has a coaxial tip on the elongated shaft element (50), as seen in figure 4; a blade (58, 59) that has a stub shaft integrally formed at the first end of the elongated shaft element (50), whereby the shaft element forms an ultrasonic blade extender, as seen in figure 4; a blade that is detachably (via 56 with 58) fastened to the first end of the elongated shaft element, whereby the shaft element forms an ultrasonic blade extender, as seen in figure 4; a blade (58, 59) that is detachably fastened to the elongated shaft element (50) through a screw threaded connection (via 56 with 58), as seen in figure 4; cam means having a cam arm mounted on the blade for pivotal movement relative thereto; as recited in columns 3-5 and seen in figures 3-7; and a plurality of axially spaced silastic rings (51) that are formed at nodes along the length of the elongated shaft element (50) and blade so as to prevent dispersion of ultrasonic waves to the surrounding elongated tubular member during operation of the instrument, as recited in column 3, lines 45-60.

10. Claims 1, 5 and 7 are rejected under 35 U.S.C. 102(a and/or e) as being anticipated by Miyawaki et al. in US Patent No. 6,193,709.

Miyawaki et al. discloses an ultrasonic surgical instrument having an end effector including blade (251a) and clamp means (282) for the engagement of tissues located therebetween; an elongated shaft element (252) having the end

effector arranged at a first end thereof; an elongated tubular member (231) extending about the elongated shaft element (252) in coaxial relationship, the clamp means (282) being movable relative to the blade (251a) and the tubular member (231), the elongated tubular member (231) having a first end in operative engagement with the end effector; a handle portion (213, 214) for receiving second opposite ends of respectively the elongated shaft element (252) and the elongated tubular member (231), the handle portion (213, 214) including finger-actuatable scissors-like thumb and finger ring structure for imparting axial displacement between the elongated shaft element (252) and the elongated tubular member (231), the tubular member biasing the clamp means (282) so as to cause the blade (251a) and clamp means (282) to selective open and close relative to each other, as recited in columns 12-24 and seen in figures 13 and 21; and a first end of the elongated shaft element and of the elongated tubular member that have cooperative camming structures for selectively opening and closing the blade and clamp means responsive to relative axial movement between the shaft element and tubular member, as recited in column 13, lines 40-67.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 6, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastri et al. in US Patent No. 6,024,750.

Mastri et al. disclose the invention with the exception of a pivotable portion including an actuating extension engageable into an aperture in the elongated tubular member for imparting axial displacement thereto responsive to rotational movement of the pivotable portion; a handle portion that includes latching pushbutton means for release of the blade and clamp assembly; and spring limiter means that are formed on the elongated tubular member so as to absorb excessive operating forces and stresses generated responsive to actuation of the handle portion.

On the other hand, Mastri et al. disclose a pivotable portion including an actuating extension engageable into an annular flange (48) in the elongated tubular member for imparting axial displacement thereto responsive to rotational movement of the pivotable portion. Since the current specification does not recite the criticality of an aperture, the annular flange of Mastri et al. can be considered equivalents since the same function is achieved. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Mastri et al. to include a protruding portion to engage with an aperture in the elongated tubular member.

Further, a handle portion that includes latching pushbutton means for release of the blade and clamp assembly and spring limiter means that are formed on the elongated tubular member so as to absorb excessive operating

forces and stresses generated responsive to actuation of the handle portion are within the scope of that disclosed by Mastri et al. and would be obvious to one with ordinary skill in the art.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Art Unit: 3743

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Hanif Bennett
Supervisory Patent Examiner
Group 3700